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Indian Standard

EYE SURGERY INSTRUMENTS — FORCEPS, EYE, DISSECTING, SERRATED, FINE — SPECIFICATION

(*First Revision*)

भारतीय मानक

नेत्र शल्य क्रिया उपकरण — चिमटियाँ, नेत्र, व्यवच्छेदो, दन्तुरित सूक्ष्म — विशिष्ट
(पहला पुनरीक्षण)

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Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 20 December 1989, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1970. The present revision includes certain modifications in order to bring the specification in line with the modern manufacturing practices. Accordingly, the tolerance clause alongwith reference to its relevant standard and requirements have been modified. Clauses on surface finish, passivation and final treatment and sampling plan have been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

EYE SURGERY INSTRUMENTS — FORCEPS, EYE, DISSECTING, SERRATED, FINE — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard covers the shape, dimensions and other requirements for dissecting forceps with fine serrated points used in eye surgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjunct to this standard:

IS No.	Title
2102 (Part 1) : 1980	General tolerances for linear and angular dimension (<i>second revision</i>)
3642 : 1978	General requirements for surgical instruments (<i>first revision</i>)
4905 : 1968	Methods for random sampling
6603 : 1972	Stainless steel bars and flats
7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 SHAPE AND DIMENSIONS

3.1 The shape and dimensions of forceps shall be as shown in Fig. 1.

3.2 Joint

3.2.1 The joints shall be block type or semi-block type conforming to 5 of Section 2 of IS 3642 : 1978.

3.3 Serrations

3.3.1 The serrations shall be transverse, raised, in accordance with Section 1 of IS 3642 : 1978.

3.4 The tolerance on dimensions of working ends shall conform to 'fine'. Class of deviation and the tolerance for remaining dimensions shall conform to 'medium' Class of deviation of IS 2102 (Part 1) : 1980.

4 MATERIALS

4.1 The forceps shall be made of stainless steel

conforming to Designation 22Cr13 or 30Cr13 of IS 6603 : 1972.

5 REQUIREMENTS

5.1 The surface of the working ends of the forceps shall be free from all defects like burrs, pits, cracks, feathres, nicks and waviness when examined under 25 × magnification. All surfaces shall be free from burrs, crevices and grinding marks.

5.1.1 The forceps shall be supplied free from residual scales, acid, grease and grinding and polishing material. Compliance with these requirements shall be checked under 2 × magnification.

5.2 The jaws shall open and close with even movement.

5.3 The guide pin shall not stick in the guide hole and shall not project beyond the guide hole when tips are fully engaged.

5.4 All sharp edges shall be rounded off.

5.5 The serrations shall register properly without overriding or sticking. The engagement of serrations shall occur first at tips and progress along on pressing the arms further.

5.6 The engagement of the serrations shall correspond with the registering of the guide pin in the guide hole.

5.7 The serrations shall be clean and bright.

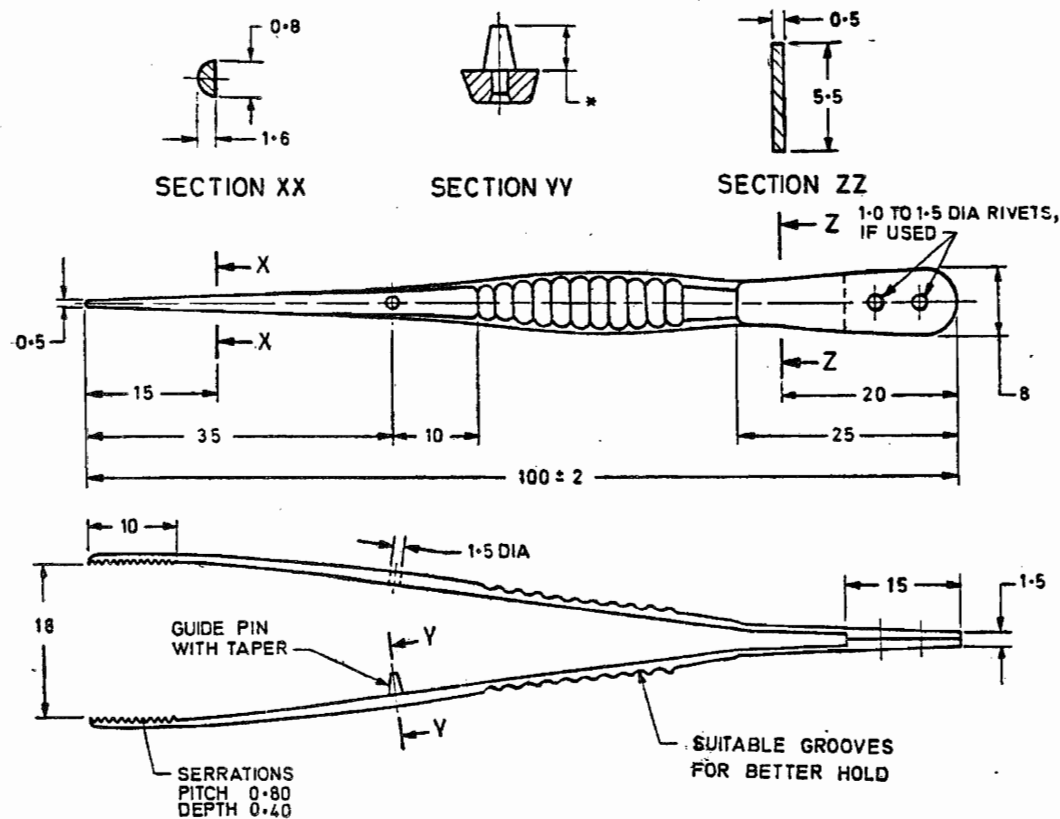
6 HARDNESS

6.1 The forceps shall have a hardness of 430 to 490 HV.

7 PASSIVATION AND FINAL TREATMENT

7.1 The forceps shall be treated by a suitable passivation process.

NOTE — Examples of methods of passivation are by electropolishing or by treating with 10% (v/v) nitric acid solution for not less than 30 min at a temperature of not less than 10°C and not exceeding 60°C. The forceps shall then be rinsed in water and dried in hot air.



*Length of pin to suit the requirements of 5.3.

All dimensions in millimetres.

FIG. 1 FORCEPS, EYE, DISSECTING WITH FINE SERRATED POINTS

8 SURFACE FINISH

8.1 The surface finish shall be one of or a combination of the following:

- mirror polished;
- reflection-reducing, for example, satin finish, matt black finish;
- an applied surface coating, for example, for insulation purposes.

NOTES

1 The satin finish shall be effected by an appropriate procedure such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish shall be uniform and smooth and it shall reduce glare.

2 Forceps for mirror finish shall be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish shall be effected by an appropriate procedure, such as polishing, brushing electropolishing.

9 TEST

9.1 Test for Engagement of Serrations

9.1.1 The test shall conform to Section 1 of

IS 3642 : 1978, with the serrations fully engaged, the tips shall not gape.

9.2 The arms of the forceps after maximum closure by manual compression shall not take a permanent set and the serrations shall continue to engage and disengage accurately and properly.

9.3 Apply force at the end of the finger grooves proximal to the tip to make the tips just touch. The force required shall be 2.0 ± 0.2 N (200 ± 20 gf approx).

9.4 Grip teased out cotton wool and pull away the gripped fibres. The fibres shall not slip out of the jaws.

9.5 Stretch a 15 micron thick latex sheet on a finger tip. Grip the sheet from the tip of the forceps and pull to a distance of 5 mm. The sheet shall be held firmly without slipping or getting punctured.

9.6 Corrosion Resistance Test

9.6.1 The forceps shall satisfy the boiling and autoclaving test as specified in IS 7531 : 1975.

The forceps shall show no sign of corrosion after the test. The forceps shall continue to work in normal manner after the test.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 The scale of sampling and criteria of conformity of the forceps to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

11 MARKING

11.1 Each forcep shall be legibly marked with the indication of the source of manufacture and the symbol 'SS' in such a way that it does not in any way impair its functioning.

12 PACKING

12.1 The forceps shall be individually wrapped in moisture-proofed or packed in polyethylene bags so as to avoid contact with one another and damage in transit.

ANNEX A

(Clause 10.1)

SAMPLING AND CRITERIA FOR CONFORMITY

A-1 LOT

A-1.1 In any consignment, all the forceps produced from the same material under similar conditions shall constitute a lot.

A-2 The number of forceps to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling

Lot Size (1)	Sample Size (2)
Up to 15	2
16 to 50	3
51 to 150	5
151 and above	8

A-2.1 These forceps shall be selected from the lot at random and in order to ensure the randomness of selection, procedure given in IS 4905 : 1968, may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the forceps selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions, material requirements, hardness, surface finish, tests and corrosion resistance. The forceps shall be considered as defective, if it fails to meet any one of these requirements. A lot shall be considered as conforming to these requirements if none of the forceps in the sample is found to be defective in any of these tests.

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